UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SERGEANTS BENEVOLENT ASSOCIATION HEALTH & WELFARE FUND, individually and on behalf of itself and all others similarly situated, Plaintiff, v. ACTAVIS, PLC, and FOREST LABORATORIES, LLC, MERZ PHARMACEUTICALS GMBH & CO., KGAA, AMNEAL PHARMACEUTICALS, LLC, TEVA PHARMACEUTICAL INDUSTRIES, INC., BARR PHARMACEUTICALS, INC., COBALT LABORATORIES, INC., UPSHER-SMITH LABORATORIES, INC., WOCKHARDT LIMITED, WOCKHARDT USA LLC, SUN INDIA PHARMACEUTICALS INDUSTRIES, LTD., DR. REDDY'S LABORATORIES LTD., and DR. REDDY'S LABORATORIES INC., Defendants.	C.A. No. 15-cv-6549 **PUBLIC VERSION**
JM SMITH CORPORATION d/b/a, SMITH DRUG COMPANY, on behalf of itself and all others similarly situated, Plaintiff, v. ACTAVIS, PLC, FOREST LABORATORIES, LLC, MERZ GMBH & CO. KGAA, MERZ PHARMA GMBH & CO. KGAA and MERZ PHARMACEUTICALS GMBH Defendants.	C.A. No. 15-cv-7488

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS FOREST AND MERZ'S MOTION TO DISMISS INDIRECT PURCHASER PLAINTIFFS' CLASS ACTION COMPLAINT AND DIRECT PURCHASER PLAINTIFFS' FIRST AMENDED CLASS ACTION COMPLAINT

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INTRODUCTION

In one hundred pages of opposition briefs, Plaintiffs fail to offer anything to rehabilitate the two critical flaws in their Complaints: (1) Plaintiffs do not and cannot allege exclusionary product hopping because the injunction issued by Judge Sweet radically changed the future factual landscape and required the continued availability of Namenda IR; and (2) Forest did not make any "large and unjustified" payments to the generic competitors to delay entry.[1]

On product hopping, Plaintiffs continue to live in an imaginary world of their own creation. Plaintiffs suggest that *Namenda I* and *Namenda II*—the decisions that specifically *prohibited and prevented* the proposed product hop—somehow show that Forest "immediate[ly] withdr[ew]" and "remov[ed] Namenda IR from all retail store shelves." DPP Opp. at 31; IPP Opp. at 7.[2] But Plaintiffs cannot just make up facts and have them stand as plausible allegations. The prior *Namenda* decisions evaluated Forest's *future* plans and issued and upheld a preliminary injunction that "prevent[ed] [Forest's] hard switch from succeeding" (*Namenda II*, 787 F.3d at 651), and that was "effective in protecting competition." Forest Br. at 2 (citing NYAG Settlement).[3] In issuing an injunction to "maintain the status quo," the District Court recognized that the "present Forest sales program"—that is, the program up through the date of the District Court decision—was "consistent with an accepted industry practice" and lawful.

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[1] Although IPPs style their opposition as against Forest and Merz Pharma GmbH & Co., IPPs in fact did not name Merz Pharma GmbH & Co. as a party to the IPP Complaint. Instead, the IPP Complaint names a non-existent "Merz" entity. That IPPs have now altered the caption in their opposition brief to list an existing Merz entity as a party does not make it one.

[2] *Namenda I* refers to *New York v. Actavis, plc*, No. 14-cv-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014); *Namenda II* refers to *New York v. Actavis plc*, 787 F.3d 638, 648 (2d Cir. 2015).

[3] "Forest Br." refers to Defendants Forest and Merz's Motion to Dismiss (ECF 85). "Gen. Br." refers to Generic Defendants' Motion to Dismiss IPPs' Complaint (ECF 81). "IPP Opp." refers to IPPs' Opposition to Defendants Forest's and Merz's Motion to Dismiss (ECF 87). "DPP Opp." refers to DPPs' Opposition to Defendants' Motion to Dismiss (ECF 69).

Namenda I, 2014 WL 7015198, at *43. The District Court entered the injunction to prevent Forest's proposed "hard switch" *ahead of generic entry*. *Namenda II*, 787 F.3d at 650. Stripped of their distortion of the prior decisions, Plaintiffs are left with only Forest's lawful public announcement about the contemplated switch and immunized government petitioning activity related to Namenda IR.

As to reverse payments, IPPs lead off with the admission that "this case is *not* about reverse payment settlement agreements, triggering the analysis provided by the Supreme Court in the landmark case *FTC v. Actavis*." But Actavis is the only basis to turn ordinary settlement agreements into something nefarious. IPP Opp. at 2 (emphasis added) (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013)).[4] Incredibly, IPPs later do an about-face and join the DPP bandwagon to label minimal payments for litigation costs as "large and unjustified" under *Actavis*. IPP Opp. at 29. But this flies in the face of *Actavis*, other cases, and FTC precedent holding that payments for "traditional settlement considerations" like litigation costs are lawful. *Actavis,* 133 S. Ct. at 2236. Similarly, the Generic Entry Acceleration Clauses are procompetitive provisions regarding the entry date, expressly allowed under *Actavis* and *In re Actos End Payor Antitrust Litigation*, No. 13-CV-9244, 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015). Strikingly, IPPs abandon any claim related to the Mylan and Orchid business agreements (IPP Opp. at 44), while DPPs grossly distort the facts to try to suggest that the Mylan Amendment was something more than "fair value for services." *Actavis*, 133 S. Ct. at 2236; DPP Opp. at 24-25. Ultimately, "labels and conclusions" cannot save these inadequate allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

[4] In their opposition, IPPs (indirect purchaser plaintiffs) call themselves "EPPs" (end payor plaintiffs), presumably to deemphasize the indirect nature of their purchases. For consistency with Forest's Motion to Dismiss, this memorandum uses the term "IPPs."

Finally, apparently admitting the complete inadequacy of each claim individually—but failing to heed the Supreme Court's *linkLine* decision—Plaintiffs seek to alchemize two inadequate allegations into an equally implausible "scheme" or "conspiracy." *But see Pac. Bell Tel. Co. v. linkLine Commc'ns*, 555 U.S. 438, 457 (2009) (refusing to "alchemize" two inadequate antitrust claims because "[t]wo wrong claims do not make one that is right."); DPP Opp. at 40-41; IPP Opp. at 34. But there was no single overarching scheme here and Plaintiffs fail to allege anything to turn a series of bilateral settlement agreements into an illegal conspiracy. Moreover, Plaintiffs never explain why the generic competitors would join a conspiracy or scheme to harm themselves.

The Complaints should be dismissed.

ARGUMENT

I. PLAINTIFFS FAIL TO STATE A CLAIM FOR PRODUCT HOPPING

A. There Was No Hard Switch Product "Hop" from Namenda IR to Namenda XR Because the Injunction Prevented the Hard Switch

Plaintiffs concede that illegal product hopping involves "withdrawing a successful drug from the market," which forces patients to switch to the new version. IPP Opp. at 10, 13-14 (citing *Namenda II*, 787 F.3d at 653-54, and quoting *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979)). Nonetheless, Plaintiffs resort to the fiction that Namenda IR was actually removed from the market, even though their own allegations fail to offer anything to support such a conclusion. IPP Opp. at 21 ("Forest's removal of Namenda IR from retail shelves . . ."); DPP Opp. at 31 (Forest announced the "immediate withdrawal of Namenda IR"). But Namenda IR was not "immediately withdraw[n]"—the February 2014 announcement stated that the cessation would occur in August, which the Company later postponed again. Forest Br.

at 11-12. Indeed, Forest *never* removed Namenda IR from the market, and Plaintiffs' bare conclusion to the contrary is at odds with reality and supported by nothing.

Alternatively, Plaintiffs' hard switch theory relies on three discrete acts: (1) Forest's truthful February 2014 announcement of plans to discontinue Namenda in the future; (2) Forest's notification to the Centers for Medicare and Medicaid Services ("CMS") about Namenda IR; and (3) Forest's signing an exclusive distribution agreement with Foundation Care for Namenda IR. DPP ¶¶ 87, 238; IPP ¶¶ 95, 195. But these actions cannot constitute an illegal "hard switch" because Namenda IR was always available for purchase, and the Foundation Care distribution plan was never implemented due to the injunction.

1. The Court Should Not Accept Plaintiffs' Blatant Inaccuracies About the *Namenda* Decisions

Plaintiffs misrepresent the holdings of *Namenda I* and *Namenda II* to support the plausibility of their product hop claims. DPP Opp. at 28-35; IPP Opp. at 9-16. But the Court is not required to accept the blatant inaccuracies about the removal of Namenda IR that are contradicted by the injunction. *See Poindexter* v. *EMI Record Grp. Inc.,* No. 11 Civ. 559, 2012 WL 1027639, at *2 (S.D.N.Y. Mar. 27, 2012) (citation omitted) ("If a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control . . . ."). For example, it is indisputable that Forest *never implemented* distribution through Foundation Care because of the standstill agreement during the injunctive action and then the injunction itself. *See, e.g.*, DPP ¶ 186; IPP ¶ 139; *Namenda II*, 787 F.3d at 648; Order ¶¶ 1, 3, *New York v. Actavis, plc*, No. 14-CV-7473 (S.D.N.Y. Dec. 15, 2014), ECF 84. But Plaintiffs continue to equate the Foundation Care contract with withdrawal. IPP Opp. at 7 ("Forest . . . ma[de] Namenda IR significantly more difficult to obtain by removing Namenda IR from all

retail store shelves effective January, 2015 by requiring Alzheimer's patients use a mail-order-only pharmacy–Foundation Care.").

2. The Injunction Prevented the Hard Switch and Forest Continued Its Lawful Efforts to Promote Namenda XR

Plaintiffs' argument that the facts alleged here are identical to the facts in *Namenda I* and *Namenda II* (DPP Opp. at 28; IPP Opp. at 11-12) fails because the NYAG sought, and ultimately obtained, a preliminary injunction preventing the very conduct at issue in that action: the future removal of Namenda IR from the market prior to generic entry. Plaintiffs incorrectly argue that the prior *Namenda* decisions found that Forest engaged in an illegal "hard switch" product hop. DPP Opp. at 28; IPP Opp. at 12, 13. In reality, however, *Namenda I* held, and *Namenda II* affirmed, that there was a substantial likelihood that Forest's *planned* strategy would violate the antitrust laws *if* allowed to be effectuated, and thus the injunction prevented any anticompetitive effects. *See* NYAG Settlement at 2, 3 (Recognizing that the "[i]njunction was effective in protecting competition in the relevant market and permitting lower cost generic drugs to enter the market in July 2015 and subsequently."). When the prior *Namenda* decisions are put in the proper context, it is clear that the issues raised in this action are distinct from the NYAG action, and the prior *Namenda* decisions mandate dismissal of Plaintiffs' product hopping claims here.

a. *Namenda I* Evaluated Proposed Future Conduct and Held that the "Present Forest Sales Program" Was Within "Accepted Industry Practice"

The opening sentence of *Namenda I* framed the issue: "New York . . . has moved . . . *to preliminarily enjoin [Forest] from engaging in antitrust violations by discontinuing the current sales of the Forest drug Namenda IR . . . .*" *Namenda I*, 2014 WL 7015198, at *1 (emphasis added). Contrary to Plaintiffs' contentions (DPP Opp. at 31-32), the District Court never made a finding of fact or conclusion of law that the *mere announcement* of discontinuance violated the

antitrust laws. Rather, the conduct that the court concluded would be anticompetitive was *future* removal of Namenda IR or *future* distribution through Foundation Care. *Namenda I*, 2014 WL 7015198, at *39 ("The State demonstrated a substantial risk that Defendants' *limited distribution strategy* would harm competition in the memantine market.") (emphasis added).

By prohibiting Forest's plans, Judge Sweet held that the injunction would ensure the "*continuation* of sales of Namenda IR [which] adds choice to physicians, patients' health plans and insurers *and constitutes a soft switch* which has been the industry practice when introducing a new drug." *Id.* at *32 (emphases added). The court expressly recognized that Forest's sales program at the time of the injunction was legal: "*[t]he present Forest sales program is consistent with an accepted industry practice* of a soft switch when a new product is introduced, a practice that maintains consumer choice before and after generic entry into the market." *Namenda I*, 2014 WL 7015198, at *43 (emphasis added); *see also* Forest Br. at 17-19.

b. *Namenda II* Recognized that the Injunction Prevented the Hard Switch and Did Not Hold that Announcement of Discontinuation Was a Hard Switch

Plaintiffs incorrectly assert that the Second Circuit's *Namenda II* decision is "controlling law" on the issue of whether Forest's announcement about withdrawal constitutes a "hard switch." DPP Opp. at 34-35. But the issue of whether the announcement alone was somehow a hard switch was not before the Second Circuit. The issue before the court was whether the District Court abused its discretion in concluding that New York had established a substantial likelihood of success on the merits, *assuming that* Forest *had* removed Namenda IR from the market. *Namenda II*, 787 F.3d at 648.

As with the District Court, the Second Circuit was *not* evaluating whether Forest's past conduct violated the antitrust laws. In fact, the Second Circuit expressly recognized that the

District Court's findings of fact at the preliminary injunction stage were *forward-looking* statements about potential harms that could have resulted *if* the hard switch had been accomplished. *E.g.*, *id.* at 649 ("*If* Defendants forced Alzheimer's patients to switch to Namenda XR . . . ."") (emphasis added); *id*. at 655 ("Defendants' hard switch *would likely have* anticompetitive and exclusionary effects on competition . . . .") (emphasis added).

Moreover, the Second Circuit was explicit that the hard switch (if it were to happen) would have been "the combination of introducing Namenda XR into the market and *effectively withdrawing Namenda IR*" because it would force Alzheimer's patients to switch to Namenda XR. *Id*. at 654 (emphasis added). The Second Circuit first used the term "effective withdrawal" to distinguish the complete withdrawal of Namenda IR from Forest's planned limited distribution strategy through Foundation Care. *Id.* at 648 ("Although the agreement with Foundation Care makes IR available to a limited number of patients, Defendants' actions *effectively withdrew*[5] Namenda IR from the market.") (emphasis added). Thus, when the Second Circuit repeated the term "effective withdrawal" throughout the opinion, it was referring to the proposed distribution through Foundation Care. The Second Circuit never used the term "effective withdrawal" to describe Forest's February 14 announcement. Accordingly, IPPs' repeated use of "effective withdrawal" to describe Forest's announcement is disingenuous. IPP Opp. at 13 ("Forest's announcement to withdraw Namenda IR was an effective withdrawal . . . .").

Plaintiffs feign outrage that Forest describes the Second Circuit's comment that the announcement was "tantamount to withdrawal" as a passing remark. DPP Opp. at 34-35; IPP Opp. at 13. But that language had nothing to do with the court's holding that Forest's planned

[5] The Second Circuit's use of the past tense can be misleading in this context because as a result of the standstill agreement and the injunction, distribution through the Foundation Care contract never went into effect, and Namenda IR remained fully available to patients and doctors through retail stores at all times. *See supra* Section I.A.1.

limited distribution strategy would have effectively withdrawn Namenda IR, constituting a hard switch. Tellingly, the "tantamount" language appears in the *background section* of *Namenda II* and is never mentioned again. *Namenda II*, 787 F.3d at 648. Thus, Plaintiffs' characterization of the remark as "the *Namenda* court's finding" or "clearly-articulated law" (IPP Opp. at 13; DPP Opp. at 34) is simply wrong.

The Second Circuit's actual holding is that "the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition" would violate § 2 of the Sherman Act. *Namenda II*, 787 F.3d at 659. If Forest's mere announcement of discontinuation somehow were a hard switch, as Plaintiffs contend, then the injunction could not have prevented the hard switch. But this faulty proposition is contradicted by the Second Circuit's explicit holding that "the injunction prevents Defendants' hard switch from succeeding." *Id.* at 651. If Plaintiffs are correct that Forest engaged in an illegal hard switch, even though it kept Namenda IR on the market, the District Court would not have stated that "the present Forest sales program is consistent with an accepted industry practice." *Namenda I*, 2014 WL 701598, at *43.

c. Collateral Estoppel Does Not Apply Because Plaintiffs Assert Distinct Claims and There Was No Final Judgment On the Merits

IPPs argue that Forest is collaterally estopped from arguing the issue of whether its conduct was exclusionary. IPP Opp. at 12. But collateral estoppel is not applicable here because the issues are not identical, and the NYAG action did not result in a final judgment on the merits. *Interoceanica Corp. v. Sound Pilots, Inc.*, 107 F.3d 86, 91 (2d Cir. 1997) (A court may apply collateral estoppel only if "(1) the identical issue was raised in a previous proceeding; (2) the issue was actually litigated and decided in the previous proceeding; (3) the party had a full and

fair opportunity to litigate the issue; and (4) the resolution of the issue was necessary to support a valid and final judgment on the merits.") (internal quotation marks and citations omitted).

As discussed above, the issue in *Namenda I* and *Namenda II* was whether the NYAG had shown a substantial likelihood of success on the merits assuming that Namenda IR had been removed from the market or limited in distribution. Here, the issue is whether Plaintiffs have stated a monopolization claim, even though Forest was required to keep Namenda IR on the market. For the same reasons, DPPs' argument that "[a] substantial likelihood of success on the merits of averments means that those averments . . . are at least plausible" (DPP Opp. at 29) ignores the reality that the injunction radically changed the relevant factual landscape.[6]

3. Plaintiffs' Other Authorities Do Not Support a Finding that the Mere Announcement of Future Discontinuance Is an Antitrust Violation

Suboxone and *Tricor* are readily distinguishable because they involved actual product withdrawal, not *proposed* product withdrawal. IPP Opp. at 20-22 (citing *In re Suboxone Antitrust Litig.,* 64 F. Supp. 3d. 665 (E.D. Pa. 2014) ("*Suboxone*") and *Abbott Labs. v. Teva, Pharm. USA, Inc.,* 432 F. Supp. 2d 408 (D. Del. 2006) ("*TriCor*")). The issue in *TriCor* was whether consumer choice was eliminated through the introduction of a new brand name drug *accompanied by removal of an older version*. 432 F. Supp. 2d at 423. IPPs' argument that *TriCor* held that product reformulation alone was "sufficient to support an antitrust claim" is simply wrong. IPP Opp. at 20. *TriCor* recognized that "one of the benefits of competition is the introduction of new, improved products." *Id*. at 420; *see also Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) ("The elimination of choice was a critical

[6] DPPs' authorities are inapposite because in those cases this Court was deciding cross-motions for preliminary injunctions and motions to dismiss *under the same set of facts in the same action*. DPP Opp. at 29 (citing *Vaguely Qualified Prods. L.L.C. v. Metro. Transp. Auth.*, No. 15 Civ. 4952, 2015 U.S. Dist. LEXIS 138340, at *29, *31 (S.D.N.Y. Oct. 7, 2015) and *ESPN, Inc. v. Quiksilver, Inc.*, 586 F. Supp. 2d 219, 229 (S.D.N.Y. 2008)).

factor in the court's decision to deny Abbott's motion to dismiss" in *TriCor*). IPPs astonishingly argue that "Forest's *removal of Namenda IR from retail shelves* is akin to Abbott buying back its inventory in *TriCor*." IPP Opp. at 21 (emphasis added). It is unclear whether IPPs are really oblivious to the fact that Namenda IR remained on retail shelves at all times (despite specific reference to the injunction in their Complaint), or whether they are intentionally trying to mislead the Court. In either case, the Court should disregard this misstatement.

Suboxone is also readily distinguishable. The alleged anticompetitive conduct in *Suboxone* involved both product withdrawal and fabricated safety concerns relating to the older product. 64 F. Supp. 3d at 682-83 (wrongful conduct included raising false safety concerns, disparaging the older product, and removing it from the market). None of the anticompetitive conduct alleged in *Suboxone* is present here.

Finally, Plaintiffs' attempts to distinguish *Berkey*, *Solodyn*, and *Walgreen* as cases involving no product withdrawal must be rejected because this case also involves no product withdrawal. IPP Opp. at 17-19.

4. Forest's Admittedly Truthful Announcement is Protected Speech

Plaintiffs cannot plausibly allege that Forest's truthful announcement concerning its future plans, and nothing more, constitutes exclusionary conduct under the antitrust laws. DPP Opp. at 36-37; IPP Opp. at 9-14. Plaintiffs admit that Forest's February 2014 announcement was a "true statement of intent" (DPP Opp. at 16), but ignore established law that a truthful public announcement regarding future product availability is protected commercial speech.[7] *See MCI Commc'ns v. AT&T Co.*, 708 F.2d 1081, 1129 (7th Cir. 1983) (First Amendment protects truthful

[7] Inconsistently, Plaintiffs also argue that the District Court "required that Defendants correct that [February 2014] announcement." DPP Opp. at 35. Nothing in the District Court's opinion or the injunction made any reference to a "correction" of the February 2014 announcement.

speech reflecting "expectations about future quality or availability where that expectation is both actually held in good faith and objectively reasonable.") (quoting 3 Phillip Areeda & Donald Turner, *Antitrust Law* ¶ 738 p. 284 (1978)).

Plaintiffs cite nothing to support their novel theory that a "true statement of intent" violates the Sherman Act. *See In re Delta/Airtran Baggage Fee Antitrust Litig.*, 733 F. Supp. 2d 1348, 1368 n.16 (N.D. Ga. 2010) ("[M]erely stating future plans—such as announcing prices—does not constitute an antitrust violation."). Such commercial speech is protected by the First Amendment. *Sorrell v. IMS Health*, 131 S. Ct. 2653, 2659-60 (2011) ("Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment."); *Sanderson v. Culligan Int'l Co.*, 415 F.3d 620, 624 (7th Cir. 2005) ("Commercial speech is not actionable under the antitrust laws."); *cf. E. R.R. Presidents' Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961) (rejecting an attempt to use the Sherman Act to punish "an attempt to persuade the legislature or the executive"). Instead, Plaintiffs rely on cases where *anticompetitive conduct* coupled with truthful speech violated the antitrust laws. *See* DPP Opp. at 36 (citing *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 U.S. 679 (1978); *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 430-32 (1990)). None of those cases supports Plaintiffs' assertion that a truthful announcement regarding future business plans can be anticompetitive simply because a court later prevents the party from executing those plans, or that the announcement "was, in essence, *verbal anticompetitive conduct* . . . lack[ing] First Amendment protection." *See Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, No. 15-Civ.-3588, 2015 WL 4720039, at *25 (S.D.N.Y. Aug. 7, 2015) (distinguishing crimes like "jury tampering, blackmail, and insider trading" where "the speech is the act" from "truthful and nonmisleading speech") (internal quotation marks and citation omitted).

Lastly, Plaintiffs' reliance on *Tricor* is also misplaced. Plaintiffs argue that *Tricor* rejected the application of the First Amendment to a "similar announcement." DPP Opp. at 38. But *Tricor* did not involve a public press release at all, but rather communications with the non-governmental National Drug Data File ("NDDF") database, regarding product code changes. The *Tricor* court was skeptical that the First Amendment applied at all, and concluded the code changes were ancillary to the anticompetitive conduct at issue in the case—namely the removal of the old product from the market. *Tricor*, 432 F. Supp. 2d at 424.

5. Forest's Communications with CMS Are Immune From Antitrust Liability Under The *Noerr-Pennington* Doctrine

DPPs incorrectly argue that Forest's communications with CMS—a government agency—are not protected under *Noerr-Pennington* because the role of CMS is merely "ministerial." DPP Opp. at 39. As Forest states in its Motion to Dismiss, the decision whether to list a drug on the Formulary Reference File ("FRF")[8] is firmly within the province of CMS, and CMS exercises considerable discretion in determining the contents of the FRF. Forest Br. at 28. CMS independently analyzes information from a number of sources and evaluates whether a drug should be listed on or removed from the FRF. *Id.* Thus, *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 370 (S.D.N.Y. 2002)—cited by DPPs (DPP Opp. at 39)—actually supports Forest. There, the court found that the act of listing a patent in the Orange Book was not protected by *Noerr-Pennington* immunity because the FDA merely acted in a "ministerial" capacity as, by law, it must publish the patent information received from the drug manufacturer. *Id.* at 371. Here, CMS exercises its discretion to determine whether to list a drug on the FRF.

[8] IPPs erroneously refer to the FRF as a "formulary" (IPP Opp. at 15), but the FRF, as its name suggests, is a *reference* tool for Part D sponsors to use in creating their formularies. *See* Formulary Reference File FAQ (April 8, 2014), https://www.cms.gov/ Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_Formulary Guidance.html.

"[A] valid and independent governmental decision . . . intervenes between the private parties' actions and these anticompetitive results." *Buspirone*, 185 F. Supp. 2d at 370.

B. Plaintiffs Fail To Plead Antitrust Injury

In arguing that they have pleaded antitrust injury, Plaintiffs once again assume a fact that they cannot plausibly allege—that Namenda IR was removed from the market, forcing patients, doctors and health care providers to purchase Namenda XR. DPP Opp. at 42-43; IPP Opp. at 23. Plaintiffs' reliance on *TriCor* and *Suboxone* to support a finding of antitrust injury fails. *Id*. *TriCor* does not even include a discussion of whether *the alleged product hop* caused antitrust injury. *Tricor*, 432 F. Supp. 2d at 430 ("Defendants make two arguments concerning antitrust injury, one for the *Walker Process* claims and a second for the sham litigation claims.").

In *Suboxone*, the court acknowledged that "generally the introduction of new products does not create antitrust injury." 64 F. Supp. 3d at 684. Nevertheless, the court found sufficient allegations of antitrust injury because the plaintiff had pled product withdrawal and fabrication of safety concerns. *Id*. at 685. Here, because the injunction assured that Namenda IR would remain on the market through generic entry, Forest's introduction of Namenda XR *increased* competition for memantine products. Absent coercion, Plaintiffs cannot establish antitrust injury through any competition-reducing aspect of Forest's introduction of Namenda XR. *See, e.g.*, *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990) ("The antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior.").

II. PLAINTIFFS CANNOT ALLEGE DELAY BEYOND EXPIRATION OF PATENT AND REGULATORY EXCLUSIVITY

A. Forest Had the Right to Exclude During Its Pediatric Exclusivity Period

1. Pediatric Exclusivity Is an Additional Exclusivity Right, Which Forest Earned

Plaintiffs' argument that pediatric exclusivity is not a patent term misses the point. DPP Opp. at 6; IPP Opp. at 28. In addition to patent exclusivity, a pharmaceutical innovator is eligible for Congressionally-conferred periods of regulatory exclusivity—such as pediatric exclusivity—as a reward for addressing unmet therapeutic needs by conducting costly clinical trials. Pediatric exclusivity was intended by Congress to give pharmaceutical innovators an incentive to test in children "medications which they intend to market primarily for adults and whose use in children is expected to generate little additional revenue." S. REP. NO. 105-43, at 51 (1997).

Pediatric exclusivity attaches at the end of other regulatory exclusivity periods and at the end of patent terms where there are patents covering the drug. 21 U.S.C. § 355a(b), (c). Congress used different markers to begin the tolling of pediatric exclusivity rights to make the benefit meaningful for patent holders, as tolling the right solely from the end of regulatory exclusivity periods would have failed to incentivize those whose patent rights extended beyond any regulatory exclusivity periods. *See* Feb. 12, 2016 Declaration of Kristen O'Shaughnessy ("KO Decl. II") Ex. 17 at 19 (Statement of Senator Mike DeWine) ("The market exclusivity extension only works as a pediatric testing incentive if a company has an existing patent to which we can *attach an additional 6 months of market exclusivity*.") (emphasis added).

Both the FDA and the courts have recognized that regulatory exclusivity periods are negotiable rights which can be relinquished in exchange for consideration. *See, e.g.*, *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 2 (D.D.C. 1997) (deferring to FDA's interpretation

that first-filer was permitted to waive its generic exclusivity period). Indeed, the Federal Circuit has explicitly recognized that a drug manufacturer involved in patent litigation can grant a license covering its pediatric exclusivity period. *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1344 (Fed. Cir. 2015). Contrary to Plaintiffs' assertion (DPP Opp. at 8), the *AstraZeneca* court did not require that the patentee defeat the generic before granting such a license.

Plaintiffs further misrepresent the holding in *AstraZeneca*. Although, the court held that the plaintiffs were not entitled to *damages* under Section 284 of the Patent Act for sales during the pediatric exclusivity period, the Court did not hold that a patentee had no rights to grant a license or collect royalties during the pediatric exclusivity period. *Id.* at 1344, 1354. Plaintiffs also cite *Altana Pharma AG v. Teva Pharms. USA, Inc.*, No. 04-2355, 2012 U.S. Dist. LEXIS 79166 (D.N.J. June 7, 2012). But *Altana* addressed a patentee's ability to collect royalties during the pediatric exclusivity period, and the court expressly acknowledged that pediatric exclusivity "provides that, for six months after the patent on the drug expires, it will not permit anyone else, subject to certain exceptions, to market the finished drug product described in the NDA." *Id.* at *8-9. Whether the collection of royalties in *Altana* was patent misuse has no bearing on the issues here.

2. The *Brulotte* Per Se Rule Does Not Apply Here

DPPs invoke *Brulotte v. Thys Co.*, 379 U.S. 29 (1964) and *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401 (2015), (DPP Opp. at 5-6, 8, 45), but those cases address only the narrow issue of whether a patentee can lawfully collect royalties post-patent expiration *under the patent laws* when its only lawful exclusionary rights are patent-based. But Forest was also entitled to an additional six months of pediatric exclusivity. *Brulotte* does not apply where the party collecting royalties has a separate, lawful basis to exclude competition. *See Zila, Inc. v. Tinnell*, 502 F.3d

1014, 1023-1024 (9th Cir. 2007) (declining to extend *Brulotte*'s prohibition against post-expiration patent royalties to payments for rights arising out of the Canadian patent regime). Moreover, *Kimble* (which confirmed the *Brulotte* rule) decided only the patent law issue and expressly disavowed antitrust principles. *Kimble*, 135 S. Ct. at 2413 ("*Brulotte* is a patent rather than an antitrust case. . . . [P]atent (not antitrust) policy gave rise to the Court's conclusion"). Accordingly, *Brulotte* and *Kimble* do not support Plaintiffs.

B. Forest Did Not Forfeit Its Exclusivity Rights By Settling Its Patent Litigation

Plaintiffs acknowledge that Forest would have been entitled to six months of pediatric exclusivity had it won its patent suit, but nonetheless argue that Forest's reservation of its pediatric exclusivity rights under the settlements was a "*per se* unlawful market division." DPP Opp. at 7. Plaintiffs cite no support for this proposition and instead apparently rely upon a crabbed interpretation of 21 U.S.C. § 355a(c)(1)(B)(ii). But the Southern District of New York has already rejected Plaintiffs' reading of the statute. As explained in Forest's Motion to Dismiss, in *In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 368, 378 (S.D.N.Y. 2007), *aff'd*, 536 F.3d 1361 (Fed. Cir. 2008), the court held that a patentee can enforce its pediatric exclusivity period in the absence of such a court decision. *Id.* ("Simply because the statutory provisions do not address the specific fact pattern before us does not mean that Astra is not entitled to the six-month period of market exclusivity that it earned by conducting the requested pediatric studies."); *see also Ranbaxy Labs. Ltd. v. U.S. Food & Drug Admin.,* 307 F. Supp. 2d 15, 20-21 (D.D.C. 2004) (pediatric exclusivity applied when patent litigation was unresolved prior to patent expiry).

Indeed, the *Omeprazole* court found such an "interpretation of the statutory provisions would create an anomalous result that is at odds with Congress's goal in enacting § 355a." 490

F. Supp. 2d at 379. Congress addressed three scenarios in the pediatric exclusivity statute—where there is no patent and only regulatory exclusivity (21 U.S.C. § 355a(c)(1)(A)), where there is a patent and there is no suit or Paragraph IV certification (21 U.S.C. § 355a(c)(1)(B)(i)), and where there is a patent and there is a suit pursuant to a Paragraph IV certification (21 U.S.C. § 355a(c)(1)(B)(ii)). Plaintiffs' argument that the exclusivity under 21 U.S.C. § 355a(c)(1)(B)(ii) would attach not after completion of pediatric trials but *only* after the patent(s) have been litigated to the bitter end would mean that an innovator drug manufacturer has fewer rights in settling patent litigation than it would under any other scenario contemplated under the statute. Plaintiffs cite nothing in the legislative record that indicates such a Congressional intent. And Plaintiffs' interpretation of the statute would undermine Congress's intent in creating the pediatric exclusivity period by imposing an obligation on manufacturers to litigate patent cases to completion before receiving pediatric exclusivity, assuming that timeline is even feasible in all cases.

The FDA has explained that in the case of statutory ambiguity, legislative silence should be interpreted "to allow an alternative course of action more favorable to the beneficiary of the government act" and a plain meaning approach should consider the "statutory context, structure, and purpose among other things." KO Decl. II Ex. 18 at 4, 7-8 (Letter from the FDA). Here, Plaintiffs seek to interpret an ambiguity in the statute *against* the beneficiary. This approach contradicts the one taken by the FDA and should be rejected. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1352 (Fed. Cir. 2003) ("Deference is due to an administrative agency's regulations particularly when the subject matter of the regulatory authority is a 'highly detailed' regulatory program to which the agency has brought its 'specialized expertise,' . . . a characterization that aptly describes the FDA's role in the context of the regulatory scheme created pursuant to the

Hatch-Waxman Act").

C. Pediatric Exclusivity Applied Retroactively to the ANDAs Here

1. Pediatric Exclusivity Was Timely Granted

Plaintiffs make much of the fact that the FDA granted pediatric exclusivity after the settlement agreements were entered here. DPP Opp. at 6-7; IPP Opp. at 28. But pediatric exclusivity applies to all ANDAs provided that the FDA determines that the NDA holder is eligible for pediatric exclusivity more than nine months prior to the expiration of the relevant patent, as the FDA did here. *See* Forest Br. at 52 n.32. Courts have rejected the claim that the FDA cannot apply such timely-granted pediatric exclusivity periods retroactively. *See, e.g.*, *Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236, 242-43, 253 (D.D.C. 2002).

2. Generics Obtained Final Approval Only After Notifying the FDA of the Settlement Agreements and Pediatric Exclusivity Waivers

Plaintiffs argue that the settling generics had final approval before the grant of pediatric exclusivity, and that Forest fails to explain how the FDA could have granted approval during pediatric exclusivity. DPP Opp. at 6. This ignores the simple fact that the FDA granted final approval only after receiving notification that the patent litigations had been settled. *See, e.g.*, KO Decl. II Ex. 19 (letter from FDA noting that Dr. Reddy's Laboratories ("DRL") had "notified the agency that Forest Laboratories, Inc. and DRL agreed to the dismissal of this case, making [DRL's] ANDA eligible for approval.").[9]

Moreover, the generics' final approval dates do not speak to when the generics could have *lawfully* entered under the terms of their patent settlement agreements. Under the

[9] *Ranbaxy Labs., Ltd. v. Burwell*, 82 F.Supp.3d 159 (D.D.C. 2015) is therefore inapposite. It concerned the FDA's right to revoke tentative approvals upon discovery of errors in the approval process and gross violations of good manufacturing practices at the Plaintiffs' facility.

settlements, the generics were not permitted to enter on a fixed date but rather were licensed to enter on the later of (a) a three-month early entry date, or (b) the date of final approval:

> **1.16 "Launch Date"** shall mean the later of: (a) 3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Execution Date; or (b) the date that [generic] obtains final approval from the FDA of the [generic] ANDA, unless accelerated as described herein.[10]

Therefore, had the '703 Patent not been subject to pediatric exclusivity, the settling generics would have been able to lawfully enter the market as early as January 2015. The fact that all waited until July 2015 shows that the generic competitors agreed with Forest's position that pediatric extension was applicable.

Further contradicting Plaintiffs' theory is the fact that the FDA required confirmation from settling generics that they were licensed to enter during the pediatric exclusivity period, including from Dr. Reddy's Laboratories which had held final approval since 2010. *See* KO Decl. II Ex. 20 (letter notifying FDA of Forest's waiver of patent and pediatric exclusivity to the extent necessary for launch of Dr. Reddy's products as permitted by terms of settlement agreement); KO Decl. II Ex. 21 (similar letter regarding Forest's waiver of patent and pediatric exclusivity for Upsher-Smith's products). The letters, copied to the particular generic entrants, stated that "[redacted]" and that the patent therefore "[redacted]." KO Decl. II Exs. 20, 21 at 2. Moreover, in granting final approval to an ANDA during the pediatric exclusivity period, the FDA stated, "[redacted]. KO Decl. II Ex.

[10] Dec. 22, 2015 Declaration of Kristen O'Shaughnessy ("KO Decl.") Ex. 1 § 1.14; *id.* Ex. 2 § 1.13; *id.* Ex. 4 § 1.12; *id.* Ex. 5 § 1.12; *id.* Ex. 6 § 1.15; *id.* Ex. 7 § 1.14; *id.* Ex. 8 § 1.16; *id.* Ex. 10 § 1.12; *id.* Ex. 11 § 1.14; *id.* Ex. 13 § 1.13.

22.

D. The Settlement Agreement Did Not Create a 180-Day Bottleneck

1. Second-Filers Entered Upon Exclusivity Expiration in October 2015

Plaintiffs suggest that there was a "180-day exclusivity bottleneck to generic competition." DPP Opp. at 10. However, as Forest explained, second-filers, including Torrent, were able to enter with their generic products upon expiration of Forest's patent and regulatory exclusivity periods in October 2015, only three months after the first-filers entered the market. Forest Br. at 59-60. Plaintiffs fail to rebut these arguments in their opposition briefs, or to offer any alternative explanation of their "bottleneck" theory.

2. Settling Generics Are Not Required to Forfeit Their Generic Exclusivity Period

Plaintiffs argue that Forest should have "required" the settling generics to convert to Paragraph III certifications so that (1) they would be subject to pediatric exclusivity, and (2) there would be no bottleneck. DPP Opp. at 10. But if the settling generics had been compelled to convert to Paragraph III certifications here, under § 355a(c)(B)(i)(II), they would have been ineligible to enter the market before the expiration of the six month pediatric exclusivity period in October 2015—that is, three months after the date on which they actually entered. Plaintiffs' proposed solution to the alleged anticompetitive conduct would therefore have *harmed* consumers because generic entry would have been three months later.

Moreover, Plaintiffs' argument makes sense only if Congress had intended a generic's right to a 180-day exclusivity period and an innovator's right to pediatric exclusivity to be mutually exclusive. Under Plaintiffs' analysis, *either* a generic is required by settlement to convert to a Paragraph III certification and therefore forfeit the 180-day exclusivity period so that an innovator can enjoy its pediatric exclusivity period, *or* the generic is permitted by settlement to

maintain its Paragraph IV certification and therefore enjoy its 180-day exclusivity period, but the innovator has then forfeited its pediatric exclusivity period. That is, one party must waive the benefits Congress intended it to have in favor of the other. Because Plaintiffs offer no support for their strained interpretation of legislative intent, this Court should reject it.

E. IPPs Improperly Seek to Raise Unpleaded Pediatric Exclusivity Arguments for the First Time in Their Opposition

IPPs' argument that Forest improperly delayed generic competition during the pediatric exclusivity period was improperly raised for the first time in their Opposition, and should therefore be rejected. *Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir. 1998); *see also Ifill v. N. Y. Court Officers Ass'n*, 655 F. Supp. 2d 382, 393 (S.D.N.Y. 2009) ("[Plaintiff] may not amend his complaint to add new claims by raising them for the first time in his motion papers."). IPPs argue that their Complaint "sufficiently alleges that Forest improperly extended its legal monopoly . . . beyond the expiration date of the '703 Patent." IPP Opp. at 26 (citing IPP ¶¶ 74, 75, 85, 87). But (in contrast to the DPP Complaint), IPPs' Complaint does not contain a single allegation that Forest's maintenance of its pediatric exclusivity period constituted improper generic delay.

III. THE ANDA SETTLEMENT AGREEMENTS DO NOT GIVE RISE TO REVERSE PAYMENT ANTITRUST CLAIMS

A. Plaintiffs Allege No "Large" And "Unjustified" Reverse Payment

IPPs have apparently abandoned any allegation of an illegal reverse payment under *Actavis*. IPP Opp. at 26 ("[T]he EPP has not alleged that Forest and the Generics entered into a reverse payment settlement agreement or any side deals, so there is no need for this Court to

activate *Actavis*."). If their claims regarding alleged payments in the ANDA Settlements do not fit the *Actavis* paradigm, IPPs have no basis to challenge those payments as anticompetitive.[11]

DPPs fill multiple pages describing the uncontested holding in *Actavis* that reverse payments have the *potential* to be anticompetitive and therefore warrant antitrust scrutiny in *certain* circumstances. DPP Opp. at 18-20. But after the long windup, DPPs fail to deliver because those circumstances—large and unjustified reverse payments—are not present here.[12]

DPPs argue that "[w]hether . . . reverse payments are 'large and unjustified' under *Actavis* is an issue of fact inappropriate for disposition at the pleading stage." DPP Opp. at 3. But in attempting to side-step the requirement of pleading a "large and unjustified" payment, DPPs misrepresent *Actavis*, which held that *only if* a reverse payment can be reasonably construed as large and unjustified should it be subject to antitrust scrutiny. 133 S. Ct. at 2237; *see also King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015) (only "when [a payment] represents an *unexplained large* transfer of value . . . may [it] be subject to antitrust scrutiny" as set forth by *Actavis*) (emphasis added).

Elsewhere, DPPs concede that they must plausibly allege a "large" reverse payment, but they wrongly assert that their threadbare allegation that the value of payments "totaled many

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[11] That said, IPPs seem confused about the nature of their own allegations, elsewhere suggesting that they are bringing a "reverse payment" claim. *Compare* IPP Opp. at 25 ("The EPP has not pled any reverse payment agreement claims"), *and id*. at 2 ("this case is not about reverse payment settlement agreements"), *with id*. at 29 ("The EPP's allegations are sufficient to support that the acceleration clause is a reverse payment"), *and id.* at 31 ("As the End Payor Plaintiffs allege . . . Forest's reverse payment—the acceleration clause—was [valuable]"). In any event, for the reasons discussed in this section, IPPs' allegations fail under *Actavis*.

[12] DPPs request permission for leave to amend their Complaint if the Court determines the level of detail in their Complaint is insufficient. DPP Opp. at 23 n.18. However, as is clear from the face of the ANDA Settlements, amendment would be futile because the agreements contain no large reverse payments. *See* Forest Br. at 35-40; *Kropelnicki v. Siegel*, 290 F.3d 118, 130-31 (2d Cir. 2002) (leave to amend futile where amended complaint would "merely add[] to [plaintiff's] original complaint the facts asserted in her opposition papers to defendants' motion to dismiss.").

millions of dollars" is sufficient.[13] DPP Opp. at 23. DPPs have identified no case in which a court has allowed such vague reverse payment allegations to survive.[14] On the contrary, courts have readily dismissed cases that provide insufficient allegations of large reverse payments. *See Actos*, 2015 WL 5610752, at *19-20 (rejecting allegation of reverse payments worth "hundreds of millions" of dollars); *In re Effexor XR Antitrust Litig.*, No. 11-md-5479, 2014 WL 4988410, at *21-23 (D.N.J. Oct. 6, 2014) (reverse payment allegations insufficient); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 544-546 (D.N.J. 2014) (same).

Relying on non-reverse payment cases, DPPs incorrectly suggest that procompetitive justifications should not be considered when determining whether Plaintiffs sufficiently allege the existence of reverse payments. DPP Opp. at 22. But as DPPs concede, to determine if there was a reverse payment under *Actavis*, the court must consider "the value of the goods, services, or other consideration provided by the claimed infringer to the patent holder." *Effexor XR*, 2014 WL 4988410, at *22; DPP Opp. at 23 n.16 (quoting *Actavis*, 133 S. Ct. at 2227) ("Under *Actavis*, the determination of whether a payment is 'large'. . . is measured by . . . its independence from other services for which it might represent payment, and the lack of any other convincing justification.").

[13] IPPs nonsensically argue that the Court can infer that there was an "exceptionally large" payment simply because Namenda IR "generated $1.5 billion in annual sales in 2013." IPP Opp. at 30. But IPPs' proposed inference lacks support in common sense and the law.

[14] Although DPPs cite *Aggrenox* for the proposition that they need not provide "very precise" figures at the pleading stage, *Aggrenox* allowed the claims to survive the motion to dismiss only because "the complaints [made] specific allegations about the terms of the settlement and their relative value that are plausible on their face." 94 F. Supp. 3d 224, 243-44 (D. Conn. 2015) (alleging reverse payments including $4 million in cash, $120 million in guaranteed royalties, and $2.5 million per year for co-promotion efforts that plaintiffs alleged exceeded the value of the services). DPPs make no such specific allegations in their Complaint.

1. Small Payments for Avoided Litigation Costs are Not Reverse Payments Under *Actavis*

As set forth in Forest's Motion to Dismiss, *Actavis* held that reverse payments reflecting litigation costs do not present antitrust concerns, and both the FTC and the courts have adopted a safe harbor for litigation costs. *See* Forest Br. at 37; *see also In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015) ("[P]ayments smaller than avoided litigation costs are presumptively not large and unexplained under *Actavis*, and represent a *de facto* safe harbor . . . .").

DPPs have no response to the safe harbor described in *Cephalon* (*see* Forest Br. at 37), opting to ignore the case altogether. Rather, DPPs contend that there is no safe harbor under *Actavis* simply because the Court did not "provide any specific dollar amount" for one. DPP Opp. at 26. But this narrow interpretation is at odds with the Court's holding that settlement payments for avoided litigation costs do not raise the same antitrust concerns as payments to avoid the risk of patent invalidation. *Actavis*, 133 S. Ct. at 2236; *see also Actos*, 2015 WL 5610752, at *19 ("payment is justified if it 'reflects traditional settlement considerations'") (citation omitted); *Effexor XR*, 2014 WL 4988410, at *23 ("settlements that take 'commonplace forms'" are not reverse payments) (citation omitted).[15]

Moreover, DPPs inappropriately aggregate the payments for litigation costs across all ANDA Settlements to conclude that the total payments exceed $[redacted] and therefore surpass any $7 million safe harbor. DPP Opp. at 26. However, DPPs provide no support for such aggregation, and at least one court has credited evidence that "the average litigation costs for

[15] For their part, IPPs apparently concede that the payments for attorneys' fees and costs in the ANDA Settlements do not constitute reverse payments, arguing instead that the anticompetitive payments at issue are the Generic Entry Acceleration Clauses. IPP Opp. at 30. As discussed below, acceleration clauses are not illegal reverse payments under *Actavis*; *see also* Forest Br. at 37-39.

patent cases with more than $25 million at stake are approximately $5.5 million *per party*." *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015) (emphasis added); *see also Actavis*, 133 S. Ct. at 2243-44 (Roberts, J., dissenting) (patent infringement litigation can be as much as $10 million per suit). Regardless of whether the typical litigation costs for a patent litigation are $5.5 million, $7 million, $10 million, or more, the ANDA Settlements provided litigation costs from $[redacted] to $[redacted], well below any of those amounts. *See* Forest Br. at 9 n.11.

DPPs additionally take an isolated reference in *Actavis* to "payor's anticipated future litigation costs" to mean that payment for the payee's litigation costs are subject to antitrust scrutiny. DPP Opp. at 26. But DPPs' interpretation is at odds with the Supreme Court's statement that "[w]here a reverse payment *reflects traditional settlement considerations*, such as avoided litigation costs . . . there is not the same concern" that the payment is anticompetitive. *Actavis*, 133 S. Ct. at 2236 (emphasis added). Compensation for already-expended litigation costs is a traditional settlement consideration, and is precisely the type of routine settlement term that does not raise antitrust concerns. *Lipitor*, 46 F. Supp. 3d at 523 ("[The generic's] prior litigation costs may be deducted from the total payment made by [the brand]."). [16]

2. Generic Entry Acceleration Clauses Are Not Payments, Let Alone "Large and Unjustified" Reverse Payments

As set forth more fully in both Forest's and the Generic Defendants' Motions to Dismiss, a Generic Entry Acceleration Clause is precisely the type of settlement term "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration" endorsed as

[16] Furthermore, DPPs mischaracterize the litigation costs that Forest agreed to pay in the ANDA Settlements. [redacted] *See* KO Decl. Ex. 1 § 2.5; *id.* Ex. 2 § 2.5; *id.* Ex. 4 § 2.5; *id.* Ex. 5 § 2.5; *id.* Ex. 6 § 2.5; *id.* Ex. 7 § 2.6; *id.* Ex. 8 § 2.5; *id.* Ex. 10 § 2.5; *id.* Ex. 11 § 2.5; *id.* Ex. 13 § 2.5.

lawful by *Actavis*. *See* Forest Br. at 37-39; Gen. Br. at I.A.1; *Actavis*, 133 S. Ct. at 2237. Indeed, Judge Abrams in this district recently provided a thoughtful analysis of similar settlement terms, and held that there is no "plausible basis for viewing [acceleration clauses] as anticompetitive." *Actos*, 2015 WL 5610752, at *15.

Plaintiffs' only response to the well-reasoned *Actos* decision is that the court was simply wrong. IPP Opp. at 29 ("[T]he *Actos* court failed to understand that an acceleration clause can be anticompetitive"); DPP Opp. at 18 ("*Actos* does not appear to comport with the Second Circuit[] . . . ."). But Plaintiffs can point to *no* court that has *ever* found a Generic Entry Acceleration Clause to constitute a reverse payment, and this Court should not be the first to do so.[17]

B. The Business Agreements with Mylan and Orchid Cannot Constitute Unlawful Reverse Payments under *Actavis*

IPPs apparently concede that the Mylan and Orchid agreements are legal because IPPs make no arguments that the agreements included large, unexplained payments. In fact, IPPs seem to abandon any claims with respect to those agreements altogether. IPP Opp. at 44 ("neither Mylan nor Orchid are [sic] defendants in this case"). DPPs similarly seem to concede that the milestone payments contemplated in the Orchid Agreement were not illegal reverse payments. DPPs merely parrot the monetary amounts discussed in Forest's Motion (DPP Opp. at 24), but do not contest Forest's argument that the "small payment to Orchid—subtracted by the value provided to Forest—simply is not a large and unjustified reverse payment on the face of the agreement." Forest Br. at 50.

[17] Lacking a plausible argument that the Generic Entry Acceleration Clauses constitute reverse payments, Plaintiffs resort to arguing that they form the basis of a conspiracy. That argument, discussed *infra* Section IV.A, is similarly meritless.

1. The Mylan Amendment Contained No Reverse Payment

DPPs do not dispute that the $[redacted] payment in the Mylan Amendment was fair value in consideration for Mylan agreeing to take on all manufacturing responsibility for the authorized generic version of Lexapro ("Lexapro AG") and for bearing the costs to have an appropriate manufacturing facility qualified by the FDA. *See* Forest Br. at 47-48. However, DPPs maintain that Mylan received a reverse payment in the form of [redacted]. DPP Opp. at 25 ("[redacted]") (emphasis added).

But to support their argument, DPPs grossly mischaracterize the [redacted] payments. DPPs' figures improperly assume Forest would have received [redacted] under the original agreement. In fact, the original agreement provided Forest [redacted] (KO Decl. Ex 14 § 6.1).[18] [redacted] payments under the amendment were calculated according to [redacted] (*id.* Ex. 15 § 6.1). When one compares the original [redacted] to the [redacted] under the amendment, the *maximum* amount of [redacted] Mylan could have realized under the amendment was $[redacted].[19] Thus, DPPs' argument that the amendment "guaranteed" Mylan an additional $[redacted] is flat wrong.

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[18] Forest would have been entitled to [redacted] *only if* [redacted] which as the article DPPs cite makes clear, did not happen [redacted]. *See* Alaric Dearment, *Mylan Launches Generic Version of Forest Labs' Lexapro*, Drug Store News (Feb. 29, 2012), http://www.drugstorenews.com/article/mylan-launches-generic-version-forest-labs-lexapro.

[19] The Mylan Amendment entitled Forest to [redacted] As compared to the [redacted] in the original agreement, Forest would thus receive: [redacted] The differential between the [redacted] the amendment and the original agreement thus [redacted] because under either agreement, [redacted]

No "Large" Payment. Even if the Mylan Amendment could be considered to contain a reverse payment, it was not "large and unexplained." A payment is large only in relation to the remaining term of the patent and earning potential. *See Actavis*, 133 S. Ct. at 2237. Plaintiffs allege that sales of Namenda IR were $1.75 billion annually, and there were about five years remaining on the patent at the time of the settlements (DPP ¶¶ 1, 2, 99), which means the payment of up to $[redacted] was a miniscule [redacted]% of the drug's annual sales (or less than [redacted] days of the brand's sales), and a microscopic [redacted]% of the remaining expected value of the patent. This pales in comparison to the relative size of alleged payments courts have found warrant scrutiny under *Actavis*. *See, e.g.*, *United Food & Commercial Workers Local 1776 v. Teikoku Parma USA, Inc.*, 74 F. Supp. 3d 1052, 1061 (N.D. Cal. 2014) (alleged payments of $226 million, approximately 25% of the drug's annual sales in 2012); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 519 (E.D. Pa. 2010) (alleged payments of approximately 26% of the drug's annual sales in 2006).

No "Unexplained" Payment. A reverse payment is "explained" when it "reflect[s] compensation for other services that the generic has promised to perform—such as distributing [a] patented item." *Actavis*, 133 S. Ct. at 2236. As discussed in Forest's Motion to Dismiss, payment under the Mylan Amendment was explicitly "in consideration . . . for the undertakings of Mylan," which included substantial costs and responsibilities Mylan agreed to bear in order to manufacture Lexapro AG. Forest Br. at 47-48. Plaintiffs do not challenge this explanation.

C. Plaintiffs Cannot Allege Antitrust Injury Caused By the ANDA Settlements

Plaintiffs do little to rebut Forest's arguments that their allegations that the ANDA Settlements caused antitrust injury are too speculative. Forest Br. at 40-46. While Plaintiffs

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[redacted]. Therefore, the differential could never exceed $[redacted].

argue that, in general, plaintiffs can allege earlier entry through an at-risk launch, they provide no specific allegations that generics would have launched at risk *in this case.*[20] DPP Opp. at 45-46; IPP Opp. at 33. IPPs merely suggest that generics would have won the underlying patent cases because the generics challenged the '703 patent—but the unremarkable fact that generics challenged the patent says nothing about the likelihood of them *prevailing* in their challenge. IPP Opp. at 32. DPPs argue that they have alleged a but-for scenario in which generics would have entered the market earlier via procompetitive settlement agreements "i.e., without pay-for-delay." DPP Opp. at 45 n.31. But as discussed—and as IPPs seem to concede—there were *no* reverse payments in the ANDA Settlements. *Supra* Section III.A.

IPPs' cases do not support their argument that causation is simply "too factual" to decide on a motion to dismiss. IPP Opp. at 31-32. *Exxon Co., USA v. Sofec, Inc.*, does not even address pleading sufficiency, but merely considered whether a lower court's finding on proximate cause after a bench trial was in error. 517 U.S. 830, 840-41 (1996). And in *Bank of New York Mellon Trust Co. v. Morgan Stanley Mortg. Capital, Inc.*, this Court held that the causation allegations were "highly plausible," but Plaintiffs' causation allegations here are not. No. 11 Civ. 505, 2011 WL 2610661, at *7 (S.D.N.Y. June 27, 2011).

IV. PLAINTIFFS FAIL TO ALLEGE AN OVERALL CONSPIRACY OR SCHEME

A. Plaintiffs Fail to Plead a Horizontal Conspiracy Between and Among Forest and the Generic Defendants

Plaintiffs' conspiracy claims must be dismissed because Plaintiffs have not plausibly alleged that there was a "conscious commitment to a common scheme" between and among Forest and the Generic Defendants "designed to achieve an unlawful objective." *Monsanto Co.*

[20] IPPs also state without support that "several of the Generics" have a history of at risk launches, but they allege nothing of the sort in their Complaint. IPP Opp. at 33.

v. Spray-Rite Serv. Corp., 465 U.S. 752, 764 (1984).[21] Lacking direct evidence of any such agreement, Plaintiffs are left to argue that a series of routine and independently negotiated patent settlement agreements give rise to an inference of collusion. DPP Opp. at 11-17; IPP Opp. at 35-44; *see also* Gen. Reply Br. at I.C. But a conspiracy premised on independent bilateral agreements must be dismissed unless Plaintiffs plausibly allege that there was an agreement among all of the co-conspirators. *See United States v. Apple, Inc.*, 791 F.3d 290, 315 (2d Cir. 2015) ("Parallel action is not, by itself, sufficient to prove the existence of a conspiracy . . . .").

Plaintiffs cannot allege that there were any communications—let alone any sort of express agreement—among the Generic Defendants regarding settling the patent litigation with Forest. DPP Opp. at 12 (no allegations of direct evidence); IPP Opp. at 39-44; *see also* Gen. Reply Br. at I.C (negating IPPs' groundless direct evidence argument).

Plaintiffs also fail to plausibly allege circumstantial evidence of a conspiracy. *See Mayor & City Council of Balt. v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013); DPP Opp. at 10-17; IPP Opp. at 39; *see also* Gen. Reply Br. at I.C. Allegations of bilateral and independent settlement agreements with Generic Defendants, without more, are insufficient to infer concerted conduct. *See Twombly*, 550 U.S. at 556 n.4. Thus, dismissal is appropriate unless Plaintiffs can "show the existence of additional circumstances, often referred to as 'plus factors,' which, when viewed in conjunction with the parallel acts, can serve to allow a fact-finder to infer a conspiracy." *Apex Oil Co. v. DiMauro*, 822 F.2d 246, 253 (2d Cir.1987).

None of DPP's six supposed "plus factors" is sufficient to support an inference of conspiracy here. DPP Opp. at 12-13; *see also* Gen Reply Br. at 9-15 (rebutting IPP's purported circumstantial evidence). First, there was no "common motive to conspire." DPP Opp. at 12,

[21] Forest incorporates by reference the arguments in the Motion to Dismiss and Reply Briefs of the Generic Defendants showing lack of conspiracy.

Point 1. Each Generic Defendant independently negotiated with Forest to include a Generic Entry Acceleration Clause that protected their entry date without conspiracy. Gen. Br. at I.A.1; Gen. Reply Br. at I.C. Second, as discussed above, the individual settlement agreements between Forest and Generic Defendants were not "near simultaneous." DPP Opp. at 12, Point 2. Third, the fact that all first filers shared the same entry date (DPP Opp. at 12), is hardly a "plus factor" supporting an inference of collusive conduct because the first filers were entitled to enter on the same date prior to the settlements. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(aa)-(bb).

Fourth, DPPs' assertion that "Forest 'created a set of economic incentives pursuant to which the Contracts were only attractive to the [generics] to the extent they acted collectively'" is simply incorrect. DPP Opp. at 12, Point 4 (quoting *Apple*, 791 F.3d at 320); *see also* Gen. Reply Br. at I.C (demonstrating that collective action was entirely unnecessary). The Generic Entry Acceleration Clauses in each agreement independently ensured each generic manufacturer would be able to enter the market at the same time as any of its competitors. Gen. Reply Br. at I.C. None of the Generic Defendants needed to "act collectively" to get that earliest possible entry date, nor did the Generic Defendants act against their economic self-interest. *See King Drug*, 2014 WL 2813312, at *12. In *Actos*, Judge Abrams dismissed virtually identical conspiracy allegations based on independently negotiated patent settlement agreements, concluding that "Plaintiffs have not, for instance, plausibly alleged that the agreements were against Defendants' self-interest in the absence of similar behavior by its rivals." 2015 WL 5610752, at *25 (internal quotation marks omitted).

Fifth, DPPs cannot plausibly allege that the inclusion of Generic Entry Acceleration Clauses in each settlement agreement, and nothing more, supports an inference of a conspiracy. DPP Opp. at 12-13, Point 5. Indeed, in *Actos*, the court explained that "[a]n acceleration clause

by its plain [terms] merely affects the date of entry into the market—a date that can be lawfully agreed upon by the parties settling a patent infringement suit" and "[t]he practical effect of the acceleration clauses [is] to increase competition in the event that other generics entered the market earlier than contemplated by the agreement." 2015 WL 5610752, at *15-16.

Sixth, the inclusion of routine disclosure provisions in the settlement agreements does not support an inference of collusion. DPP Opp. at 13, Point 6. If every term of the settlement agreements with each of the fourteen Generic Defendants here were entirely confidential, especially with the first-filers all being in similar (if not identical) positions, negotiating new forms of settlement agreements with each Generic Defendant would have been entirely impracticable and, in practice, unadministrable. *See, e.g.*, *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 748 (E.D. Pa. 2014) (noting in "the vast majority of pay-for-delay suits" the terms of settlement agreements are disclosed to the public); *see also In re Insurance Brokerage Antitrust Litig.*, 618 F.3d 300, 329-31 (3d Cir. 2010) (disclosure of contract terms with other parties does not support an inference of a horizontal conspiracy).

Nexium does not save Plaintiffs' claims. DPP Opp. at 16-17 (citing *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231 (D. Mass. 2014)). *Nexium* involved compelling allegations of "large" payments in the form of side agreements made in exchange for the agreed-upon settlements; there are no such payments here. 42 F. Supp. 3d at 254 (assessing interdependence of settlement agreements "[e]specially in light of the significant consideration being offered by [the brand] through various side agreements").

B. Plaintiffs Cannot Revive Two Implausible Claims By Rebundling Them as an Overarching Scheme to Monopolize

Perhaps recognizing that they cannot plausibly allege either an unlawful hard switch or an unlawful reverse payment, Plaintiffs argue that their claims can still survive under a theory of

an overarching scheme to monopolize. But "overarching scheme to monopolize" is not a catch-all that parties may use to whisk baseless claims together to create an actionable one.

Plaintiffs rely on *Continental Ore* in support of their argument that independently lawful acts may be combined into an unlawful scheme. IPP Opp. at 34; DPP Opp. at 40.[22] But in *Continental Ore*, unlike here, some of the underlying conduct was independently actionable. *See, e.g.*, *Cont'l Ore Co. v. Union Carbide & Carbon Corp.,* 370 U.S. 690, 701 (1962).[23] When two claims are individually baseless, "[t]wo wrong claims do not make one that is right." *Pac. Bell Tel. Co. v. linkLine Commc'ns*, 555 U.S. 438, 457 (2009); *see also Ne. Tel. Co. v. AT&T*, 651 F.2d 76, 95 n.28 (2d Cir. 1981) (acknowledging *Continental Ore*, but holding that where certain claims are "utterly lacking," treating them collectively is improper); Phillip Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2004) ¶ 310c2 ("Where causation is completely lacking, it cannot be aggregated."); Daniel Crane, *Does Monopoly Broth Make Bad Soup?*, 76 Antitrust L.J. 663, 668 (2010) ("Shortcuts that skip the elements of different theories of exclusionary behavior and go straight to a 'cumulative effects' bottom line are prohibited."). Here, too, Plaintiffs' claims regarding the product hop and the ANDA Settlements are so utterly lacking that together they cannot produce a viable claim.

DPPs' argument that an overall scheme is actionable insofar as it seeks to combine "facts" rather than "claims" does not save their theory. First, it is disingenuous for DPPs to

[22] Although DPPs seek support in *Namenda II*, *Namenda II* provides no support because the court was looking only at the potential hard switch; the ANDA Settlements were not at issue.

[23] *See also* Areeda & Hovenkamp ¶ 310a ("[T]he Court's conclusion that the whole might be greater than the sum of its parts was not essential to the reversal, for the Court ultimately found that many of the individual allegations, once corrections were made, could have been sufficient to warrant a verdict for the plaintiff.").

argue that their hard switch and settlement agreement allegations are not "claims" when they assert them as separate claims in their Complaint. DPP ¶¶ 237-243, 251-257. Second, multiple instances of lawful *conduct* cannot be aggregated into antitrust liability. *See Eatoni Ergonomics, Inc. v. Research in Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012) ("Because these alleged *instances of misconduct* are not independently anti-competitive, we conclude that they are not cumulatively anti-competitive either.") (emphasis added) (citing *City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981)); *see also* Areeda & Hovenkamp ¶ 310c2 ("[I]f a plaintiff is found not to be injured by the anticompetitive consequences of a defendant's *conduct in each of two different situations*, the aggregation does not create antitrust injury either.") (emphasis added).

Finally, Plaintiffs' own allegations undermine any notion of an "overarching scheme," as they allege that Forest's initial plan was to implement a *legal* soft switch, and only after Forest became unsatisfied with the soft switch did it attempt to implement a hard switch. DPP ¶ 86; IPP ¶ 94; IPP Opp. at 7 ("Forest started with a soft switch, but it failed so it began implementing a hard switch in February 2014."). Plaintiffs cannot plausibly allege that the ANDA Settlements—entered into in 2009 and 2010—were part of a scheme to effectuate an unlawful hard switch, when they also allege that a hard switch was not even contemplated until 2014. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 595-96 (1986) (finding no overall scheme where plaintiffs alleged two separate conspiracies and where one "provide[d] little, if any, support" for the other); *see also* IPP Opp. at 2 ("Forest's . . . exclusionary conduct [] began in early 2014").

V. DPPS' CLAIMS ARE TIME-BARRED BY THE STATUTE OF LIMITATIONS

Plaintiffs cannot point to any overt act after July 21, 2010 to restart the limitations

period.[24] Plaintiffs also do not distinguish *Cipro* or *Grimm*, which held that the payment of allegedly "supra-competitive" prices is the "mere reaffirmation of an initial act," and "will not extend the limitations period." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 228 (E.D.N.Y. 2003); *United States v. Grimm*, 738 F.3d 498, 504 (2d Cir. 2013).

DPPs rely on *Berkey*, but *Berkey* held that when damages are "entirely speculative" at the time of allegedly anticompetitive conduct, a purchaser suing for overcharges may point to pre-limitations period acts. *Berkey*, 603 F.2d at 295-96. According to Plaintiffs, any such "speculation" dissipated when the FDA approved the first generic Namenda product in April 2010. *See* DPP ¶¶ 133, 136; IPP ¶¶ 72, 83, 146. Thus, Plaintiffs' claims are untimely.

VI. IPPs' CLAIMS ALSO FAIL UNDER INDIVIDUAL STATE LAWS

As set forth in the Generic Defendants' Reply Brief (incorporated here by reference), Plaintiffs' state law claims must be dismissed.

* * *

CONCLUSION

For the foregoing reasons, Plaintiffs' claims should be dismissed with prejudice.

Dated: February 12, 2016

Respectfully submitted,

Martin M. Toto

Martin M. Toto
Jack E. Pace III
Kristen O'Shaughnessy
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Telephone: (212) 819-8200
Facsimile: (212) 354-8113

[24] While IPPs claim Forest's alleged "product hop" occurred during the limitations period, this appeal to an event that never materialized cannot save their untimely claims. IPP Opp. at 49.

J. Mark Gidley
Peter J. Carney
WHITE & CASE LLP
701 Thirteenth Street, NW
Washington, DC 20005
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Counsel for Actavis plc, Forest Laboratories, LLC, Merz Pharmaceuticals GmbH, Merz GmbH & Co. KGaA, and Merz Pharma GmbH & Co. KGaA